

## REMARKS

Examiner Snyder is thanked for her comments concerning the prior response. It is respectfully maintained that the pending subject matter is allowable, and reconsideration and further examination are requested in light of the above amendments and the following remarks.

### **The Finality of the Office Action is Premature and Should Be Withdrawn**

Per MPEP 106.07(a), a second action may not be final “where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims, nor based on information submitted in [particular] information disclosure statement[s] . . . .” The Examiner suggested that amendments necessitated the new ground of rejection (over the Sand reference, US 6645213) that appeared in this Office Action. Respectfully, the pending claims were only amended in the previous response (dated July 1, 2011) to delete reference numerals. No substantive changes to the previously pending claims were made—the claims have the same language and scope as they did prior to the last response. Without substantive change, it cannot be said that a new ground of rejection of any of claims 1-11 was necessitated by the amendment. It is respectfully requested that the finality of the present action be withdrawn as premature.

### ***Section 102 Rejections***

#### **Claims 1-2, 4 and 6-11 are Not Anticipated by Noce**

The pending Office Action alleged that independent claim 1 and its dependent claims 2, 4 and 6-11 were anticipated by the previously-cited Noce reference. Claim 1 recites a handle, which the Office Action took to be item 22 in the Noce reference and a chamber that receives a medicinal mixture and is coupled to the handle, which the Office Action took to be item 20 in

Noce. The claim further recites “a threaded region within the handle,” which the Office Action compared to item 28 in Noce. The remarks made in the prior response are incorporated herein by reference for the sake of brevity, but are maintained to be relevant to this case.

The Examiner’s comments did not address all of the issues raised in the Applicant’s prior response. The principal position taken in the comments was that the language “insert molded” as used in the claims denotes a product-by-process, and that therefore the claim covers “only the structure implied by those steps.” Respectfully, the term should not be restricted to describing a product-by-process, but should be considered as an expression of the connection between two specific parts. As discussed throughout the present application, insert molding indicates the strong attachment between knob 12 and rod 14 (e.g. para. 32 of the application as published [US 2011/0125088]) or between insert 120 and handle 16 (e.g. para. 86 of the application as published).

To make that idea more clear, claim 1 is amended to explicitly recite the fixation of the threaded insert with respect to the handle, that results from insert molding. Noce’s item 28, interpreted as a “threaded insert” by the Office Action, is not fixed with respect to its handle 22. Noce’s mode of operation requires that item 28 be pivotable with respect to handle 22 in order to permit selective connection to and disconnection from shank 26. Accordingly, Noce not only does not show a threaded insert as recited in claim 1, but it teaches away from such a fixed threaded insert.

Dependent claims 2-11 are not anticipated on their own merit and/or by virtue of their dependence from claim 1. For example, claim 2 recites that the threaded insert includes metal or plastic. The Examiner compared item 28 of Noce with the recited “threaded insert,” and cited to column 4, lines 31-40 of Noce to reject claim 2. However, that disclosure does not discuss item

28 of Noce at all, but describes the formation of plunger 24. No disclosure was found in Noce to disclose or suggest that item 28 included metal or plastic.

The Office Action acknowledged that Noce does not show the subject matter of claim 5. However, it alleged that the reversal of shank 26 and hole 66 (alleged to be the tab and notch of the claim, respectively) would be obvious to one of ordinary skill. Respectfully, it is not seen how the shank 26 can be reversed with the hole 66 in Noce while still maintaining its taught method of operation. Shank 26 must be connected to item 46 and extend into item 20 in order to operate piston 74.

Claim 6 recites that an exterior surface of a chamber (that receives a medicinal mixture, as claim 1 recites) has at least one notch dimensioned to engage with at least one corresponding tab on an exterior surface of a handle. The Examiner's comments (p. 7) suggested that shank 26 was the "tab" of the claim, and so long that some portion of shank 26 engaged hole 66, that satisfied the claim. While it is not conceded that the claim can reasonably be interpreted in that fashion, claim 6 is being amended to recite that the notch is a curved indentation into a cylindrical exterior of the chamber. Support is found at least in paragraph 77 of the application as published. Noce does not show or suggest such structure.

As to claim 8, its subject matter is not disclosed by Noce. "[P]atent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue." MPEP 2125 (quoting *Hockerson-Halberstadt, Inc. v. Avia Group Int'l*, 222 F.3d 951, 956, 55 USPQ2d 1487, 1491 (Fed. Cir. 2000)). Moreover, even if item 46 were scaled or dimensioned according to Noce's drawings, it is clear that the axial length (left to right in Noce's Figures 1 and 2) is smaller than the diameter (top to bottom). Claim 8 is thus not anticipated.

Regarding claim 9, the Office Action referred only to Figure 2 of Noce to assert that a knob (identified as 20) has a longitudinal rectangular cavity. Claim 9 is being amended to recite a symmetrical rib as well as plural longitudinal ribs between which is the rectangular cavity. Support for the amendment is found in paragraphs 36 and 37 and associated drawings. Noce does not show the recited structure.

For at least these reasons, Noce does not show all features of claims 1-2, 4 and 6-11. Withdrawal of these rejections is respectfully requested.

### **The Pending Claims are Not Anticipated by Sand**

The Office Action rejected previously-pending claims 1-2, 4-5 and 8-13 under Section 102(b) over the Sand reference (US 6645213). Withdrawal of these rejections is respectfully requested because Sand does not show all features of these claims.

As to claim 1, Sand does not show all features of the claim both prior to and after the above-noted amendment. The Office Action compared Sand's threaded aperture 328 and advancement screw 318 to the threaded region and threaded rod recited in claim 1. However, the claim recites that the threaded rod is in threaded engagement with the threaded region. Sand's screw 318 is not and cannot be in threaded engagement with aperture 328, as shown in its Figure 25 and because Sand teaches that its items 314 and 318 must be independent of each other to enable multiple modes of delivery (col. 13, line 62-col. 14, line 38).

Thus, the amendment to claim 1 is not necessary to overcome the Sand reference. Even so, Sand also does not show or suggest fixation of the threaded region with respect to the handle. Sand teaches that the operator holds handle 306 in one hand and rotates item 314 (with its

threaded aperture 328) with respect to it (col. 14, lines 26-35). Respectfully, the Sand reference cannot anticipate claim 1, and this rejection should be withdrawn.

Claims 2, 4-5 and 8-13 depend from claim 1, and are allowable on that basis and/or on their own merit. For example, the Office Action cited to col. 13, lines 37-40 and col. 16, lines 1-3 regarding the features of claims 2 and 3. Those sections refer to handle 306, syringe body 304 and advancement screw 318, and say nothing about threaded aperture 328. Further, those sections say nothing about soft rubber.

Claim 5 recites that an exterior surface of the chamber comprises at least one tab dimensioned to engage with at least one corresponding notch on an exterior surface of the handle. If the proximal (i.e. right-most) surface of item 304 in Sand's Figure 25 are considered one or more "tabs," the notch is in an interior surface of item 306. There is no disclosure of a notch on an exterior surface of item 306, much less one that engages with the proximal end of item 304.

The subject matter of claim 8 was not discussed with respect to Sand, and so no *prima facie* case of anticipation has been shown. As noted previously, "[P]atent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue." MPEP 2125. Moreover, even if item 316 were scaled or dimensioned according to Sand's drawings, it is clear that the axial length (left to right in Sand's Figures 25-27) is smaller than the diameter (top to bottom).

Regarding claim 9, again no *prima facie* case for its rejection was presented. Further, as previously noted claim 9 is being amended to recite a symmetrical rib as well as plural longitudinal ribs between which is the rectangular cavity. Sand does not show the recited structure.

As another example, claim 13 is being amended to recites that the chamber includes an external locking mechanism having an orthogonal surface and a tab distal of said orthogonal surface, wherein the tab has a snap fit into a notch in an external surface of the handle. The projection the Examiner noted in Sand that is distal of the orthogonal surface (right-most portion of item 304) does not snap fit into a notch.

### ***Section 103 Rejections***

Claim 5 was rejected as being allegedly obvious over Noce. As noted above, however, Noce does not disclose all features recited in independent claim 1. Further, the rejection is based merely on alleged reversal of parts from claim 6, i.e. shank 26 and hole 66 (alleged to be the tab and notch of the claim, respectively). Respectfully, it is not seen how the shank 26 can be reversed with the hole 66 in Noce while still maintaining its taught method of operation. Shank 26 must be connected to item 46 and extend through hole 66 into item 20 in order to operate piston 74. One of skill in this art, with Noce's teachings, would not understand (much less be motivated) how or why to reverse shank 26 and hole 66.

Claim 3 was rejected as being allegedly unpatentable over Noce in view of U.S. Patent No. 6,802,824 to Mickley et al. Again, because Noce does not disclose all of the features recited in independent claim 1 from which claim 3 depends, this rejection should be withdrawn. Further, while the Mickley reference discusses a "handpiece housing 2" that includes "a rubber grip surface 8," it does not explicitly or inherently disclose overmolded soft rubber as in claim 3. For example, it is possible that rather than overmolding rubber, Mickley's surface 8 is otherwise applied. Consequently, Applicants respectfully request withdrawal of this rejection.

### *New Claims*

New claims 14 and 15 are being offered. Claim 14 recites that the insert-molded component includes a threaded insert with internal threads and an external surface that has a curved indentation. Support for claim 14 is shown at least in Figure 8 and paragraphs 79-82 of the application as published. Neither Noce nor Sand disclose an insert with internal threads and an external curved indentation as disclosed.

Claim 15 recites that the threaded insert includes at least one knurl or indentation parallel to the axial length of the threaded insert. Support for claim 15 is shown at least in Figure 8 and paragraphs 79-82 of the application as published. Neither Noce nor Sand disclose at least one knurl or indentation parallel to the axial length of the threaded insert as disclosed.

### **Conclusion**

The above amendments and remarks are not intended to provide an exhaustive basis for patentability or concede the basis for the rejections in the Office Action, but are simply provided to overcome the rejections made in the Office Action in an expedient fashion.

In view of the above amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and an early notice of allowance is earnestly solicited.

If after reviewing this amendment the Examiner feels that any issues remain which must be resolved before the application can be passed to issue, the Examiner is invited to contact the undersigned representative by telephone to resolve such issues.

Respectfully submitted,

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